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321	7590	04/18/2007	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			LANDAU, SHARMILA GOLLAMUDI	
			ART UNIT	PAPER NUMBER
			1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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uspatents@senniger.com

Office Action Summary	Application No. 10/660,203	Applicant(s) JOSEPH ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-59 are pending in this application. Claims **1-10, 12-41, and 43-59** are directed to the elected species. Claims 11 and 42 are withdrawn as being directed to a nonelected species.

Claim Rejections - 35 USC § 112

The rejection of claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments of 1/23/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4, 8-10, 12-13, 15-16, 25-31, 34-35, 39-41, 43-45, 52-54, 57-59 under 35 U.S.C. 102(b) as being anticipated by Krzysik (5,869,075) are maintained.

Krzysik discloses a composition comprising from about 30-90% of hydrophilic solvent, from about 10-50% of high molecular weight polyethylene glycol having a molecular weight of about 720 or greater; about 5-40% of a C14 to C30 fatty alcohol, said composition having a melting point from about 30-70C and a penetration hardness of from about 5 millimeters to 360 millimeters. See column 2, lines 1-10.

The amount of hydrophilic solvent is from about 30-90%. Suitable hydrophilic solvents include, but are not limited to, the following materials: water, propylene glycol, low molecular weight polyethylene glycols (molecular weights of less than 720 and liquid at room temperature),

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methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, glycerin, sorbitol, hydrogenated starch hydrolysate, and silicone glycols.

Additional ingredients include antiacne actives; antifoaming agents; antimicrobial actives; antifungal actives; antiseptic actives; antioxidants; astringents; colorants; deodorants; emollients; external, anesthetics, or antipruritics; film formers; humectants; natural moisturizing agents; skin conditioning agents; skin exfoliating agents (alpha hydroxy acids and beta hydroxyacids); skin protectants; solvents; sunscreens; and surfactants. See column 3, line 35 to column 4, line 10. These are added in an amount of 0.5-40%. See column 4, lines 25-30.

Further, the composition can contains 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal); and fatty esters. See column 4, lines 10-25.

Example 7 comprises 10% propylene glycol (humectant); 10% PEG-400 (compatibilizing agent); 20% PEG-1000 and 30% PEG-8000 (immobilizing agents); 10% dimethicone copolyol (silicone emollient); and 20% hydrogenated starch hydrolysate.

Example 11 comprises 35% PPG (compatibilizing agent) ; 20% PEG-8000(immobilizing agents); 10% cetyl alcohol ; 10% stearyl alcohol ; 10% hispagel (hydrogel humectant); 10% dimethicone (emollient); and 5% myristyl myristate (fatty ester oil -skin barrier agent). Note that the combination of the high molecular weight PEG and fatty alcohols read on the instant weight

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percent of the immobilizing agent. Further, the general disclosure discloses the use of high molecular weight PEG in an amount of 10-50%.

Example 12 comprises 28% PPG (compatibilizing agent); 15% PEG-8000 (immobilizing agents); 10% cetyl alcohol (immobilizing agents); 10% stearyl alcohol (immobilizing agents); 15% hydrogenated starch hydrolysate (humectant); 10% dimethicone (emollient); 7% lubrasil (dispersing agent) and 5% myristyl myristate. Note that the combination of the high molecular weight PEG and fatty alcohols read on the instant weight percent of the immobilizing agent. Further, the general disclosure discloses the use of high molecular weight PEG in an amount of 10-50%.

Note with regard to claims 28-30 and 57-59, although the prior art does not explicitly recite this property, it is the examiner's position that the prior art will have the same properties since the prior art and the instant claims are the same. Note MPEP 2112.01 II: A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

Applicant argues that Krzysik fails to disclose a composition wherein no more than 50% of the components are liquid at room temperature and no less than 50% of the components are solid at room temperature, and at least 85% of the components form a single phase. Applicant argues this is not inherent.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The examiner points out that the prior art need not explicitly recite a property to

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anticipate the instant invention. For instance, example 7 discloses a composition comprising 10% propylene glycol (humectant); 10% PEG-400 (compatibilizing agent); 20% PEG-1000 and 30% PEG-8000 (immobilizing agents); 10% dimethicone copolyol (silicone emollient); and 20% hydrogenated starch hydrolysate. The examiner points out that about 50% of the components, PEG-1000 and PEG-8000, are solid at room temperature and less than about 50% of the components, PPG and starch hydrolysate, are liquid at room temperature. The property of being solid or conversely liquid at room temperature is an inherent property of the component itself. With regard to the recitation that at least 85% form a single phase, the examiner points out that all the components in example 7 are hydrophilic except dimethicone copolyol, which is utilized in a weight percent of 10%; therefore this limitation is met.

Applicant argues that none of the examples teach 1-20% of a humectant and the amount taught exceeds this amount. Applicant argues that propylene glycol, glycerin, and sodium hydrolysates act as humectants.

The examiner points out that the instant claim language, i.e. "comprising", does not exclude other components in the composition. Thus, the composition is only required to have 1-20% of a humectant. For instance, in example 7 the composition contains the required amount of humectant such as 10% propylene glycol, which reads on the humectant. However, the instant claim language does not exclude other components such as additional moisturizing agents including hydrogenated starch hydrolysate in the composition. Moreover, the examiner points out that in example 7, the sodium hydrolysate reads on the humectant and the 10% PPG and 10% PEG-400 both read on compatibilizing. Therefore, the composition comprises 10% propylene glycol (compatibilizing agent); 10% PEG-400 (compatibilizing agent); 20% PEG-

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1000 and 30% PEG-8000 (immobilizing agents); 10% dimethicone copolyol (silicone emollient); and 20% hydrogenated starch hydrolysate (humectant). Again the examiner points out that the prior art teaches the same components in the same weight percent and therefore the properties claimed, i.e. the composition is in a single phase at 45-80° C, must be the same since “A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). 2112 wherein the examiner is required to show and reasonable rationale for inherency and the burden shifts to applicant to show the difference. The examiner provided a reasonable rationale of inherency in the office action; however applicant has not provided any evidence showing the contrary. Thus, the rejection is maintained.

The rejection of claims 1-4, 8-10, 12-13, 15-17, 21-22, 25-31, 34-35, 39-41, 43-46, 50-54, 57-59 under 35 U.S.C. 102(b) as being anticipated by Tyrell et al (20020120241) are maintained.

Tyrell et al disclose a composition comprising 28% propylene glycol (compatibilizing agent); 5% hydrogenated starch hydrolysate (humectant); 1% chitosan polymer; 25% of PEG 10,000 (immobilizing agents); 25% benzyl alcohol (immobilizing agents); 2% laureth-3 (dispersing agent); 3% laureth-4 (dispersing agent); 10% dimethicone (emollient); 1% sunflower oil; 0.8% soy sterol. See Table 1. Note that the combination of the high molecular weight PEG and benzyl alcohol read on the instant weight percent of the immobilizing agent.

Example 20 discloses a composition comprising 10% propylene glycol (humectant), 4% PEG-400 (compatibilizing agent); 5% chitosan polymer; 15% of PEG 10,000 (immobilizing

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agents); 10% benzyl alcohol (immobilizing agents); 10% emulsifying wax (dispersing agent); 20% dimethicone treated zinc oxide (emollient); 10% sunflower oil; 1% cholesterol. Note that the combination of the high molecular weight PEG and benzyl alcohol read on the instant weight percent of the immobilizing agent.

The composition has a penetration hardness of about 54 to 365 millimeters and a melting point of about 32 to 100 degrees C. See [0147].

Note with regard to claims 28-30 and 57-59, although the prior art does not explicitly recite this property, it is the examiner's position that the prior art will have the same properties since the prior art and the instant claims are the same. Note MPEP 2112.01 II: A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

Applicant argues that Tyrell fails to disclose a composition wherein no more than 50% of the components are liquid at room temperature and no less than 50% of the components are solid at room temperature, and at least 85% of the components form a single phase. Applicant argues this is not inherent.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The examiner points out that the prior art need not explicitly recite a property to anticipate the instant invention. For instance, example 13 discloses 28% propylene glycol (compatibilizing agent); 5% hydrogenated starch hydrolysate (humectant); 1% chitosan polymer; 25% of PEG 10,000 (immobilizing agents); 25% benzyl alcohol (immobilizing agents); 2%

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laureth-3 (dispersing agent); 3% laureth-4 (dispersing agent); 10% dimethicone (emollient); 1% sunflower oil; 0.8% soy sterol. See Table 1. Therefore, the composition falls within the claimed ranges of 1-40% of an emollient; 1-20% of a humectant; 30-90% of an immobilizing agent; and 1-40% of a compatibilizing agent as claimed by the instant invention. Thus, the prior art teaches the same components in the same weight percent and therefore the properties claimed, i.e. the composition is in a single haste at 45-80° C, must be the same since "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). 2112 wherein the examiner is required to show and reasonable rationale for inherency and the burden shifts to applicant to show the difference. The examiner provided a reasonable rationale of inherency in the office action; however applicant has not provided any evidence showing the contrary. Thus, the rejection is maintained.

With regard to the recitation that the composition contains no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature, the examiner points out that about 50% of the components, PEG-10,000 and benzyl alcohol, are solid at room temperature and no more than about 50% of the components, PPG, dimethicone, sunflower oil, and starch hydrolysate, are liquid at room temperature. The property of being solid or conversely liquid at room temperature is an inherent property of the component itself.

The rejection of claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, 57-59 under 35 U.S.C. 102(b) as being anticipated by WO 00/64409 to Krzyski et al are maintained.

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Krzysik et al disclose a hydrophilic composition comprising from about 10-95% of a hydrophilic solvent, from about 5-95% of a high molecular weight polyethylene glycol (preferably having a molecular weight of about 720 or greater), from about 1-30% of a C14 to C30 or greater fatty alcohol, from about 0.5-30% of humectant, from about 1 to about 20% of an emulsifying surfactant having an HLB range greater than 7, from about 0.1-10% of sterol or sterol derivative, and from about 0.1-30% of natural fats or oils. The hydrophilic composition has a melting point from about 30 °C. to about 100 °C. The composition also has a penetration hardness of from about 5 millimeters to 360 millimeters. See page 3, lines 92-105.

More specifically the hydrophilic solvent may be in an amount of 25-75%, the high molecular weight PEG in an amount of 15-50%, the fatty alcohol in an amount of 1-30%, the surfactant in an amount of 1-20%, the sterol in an amount of 0.1-10%, and the natural fat or oil in an amount of 0.1-30%. See column 7, lines 220-235. Preferably the melting point of the composition is from 50-60 degrees C and has a penetration hardness of 5-100 millimeters. See page 15.

The hydrophilic component (compatibilizing agent) is selected from water, propylene glycol (PPG), low molecular weight polyethylene glycols, glycerin, and hydrogenated starch hydrolystate. See page 5, second paragraph.

The high molecular weight PEG (the immobilizing agent) may be PEG 1400, PEG 8000, PEG 10,000. See page 5, second paragraph.

The humectant may be glycerin, sorbitol, or hydrogenated starch. See page 5, second paragraph.

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The surfactant may be glyceryl stearate, glycol stearate, or an emulsifying wax. See page 5, second paragraph.

The sterol may be soy sterol, cholesterol, or lanasterol. See page 5, second paragraph.

The natural fat or oil may be sunflower oil, borage oil, or avocado oil. See page 5, second paragraph.

The composition may comprise other additives such as antiacne actives; antifoaming agents; antimicrobial actives; antifungal actives; antiseptic actives; antioxidants; astringents; colorants; deodorants; emollients; external, anesthetics, or antipruritics; film formers; humectants; natural moisturizing agents; skin conditioning agents; skin exfoliating agents (alpha hydroxy acids and beta hydroxyacids); skin protectants; solvents; sunscreens; and surfactants. These are added in an amount of 0.5-40%. See page 16 in an amount of 0.5-40%. The examples disclose the use of an antioxidant (tocopheryl acetate) in an amount of 0.3%. Further, the composition can contains 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal); and fatty esters. See page 16.

Krzyski discloses several examples:

The composition may comprise about 42 weight percent polyethylene 200 (compatibilizing agent), about 20 weight percent polyethylene glycol 8000 (immobilizing agent); about 10 weight percent behenyl alcohol (immobilizing agent); about 10 weight percent stearyl alcohol, about 5 weight percent glycerin (humectant), about 5 weight percent glycol stearate SE (dispersing agent), about 3 weight percent soy sterol, and about 5 weight percent evening primrose oil (natural oil). see page 9, lines 285-291.

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Formula 6 discloses a composition comprising 35% PPG (compatibilizing agent); 20% PEG-8000 (immobilizing agent); 5% glycerin (humectant); 10% benzyl alcohol (immobilizing agent); 10% stearyl alcohol; 3% glyceryl stearate (dispersing agent); 3% sunflower oil (natural oil); 3% soy sterol; 10% dimethicone (emollient); 1% DC 1428.

Note with regard to claims 28-30 and 57-59, although the prior art does not explicitly recite this property, it is the examiner's position that the prior art will have the same properties since the prior art and the instant claims are the same. Note MPEP 2112.01 II: A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

Applicant argues that Krzyskil fails to disclose a composition wherein no more than 50% of the components are liquid at room temperature and no less than 50% of the components are solid at room temperature, and at least 85% of the components form a single phase. Applicant argues this is not inherent. Applicant argues that Krzysik does not teach the instant amount of the immobilizing agent.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The examiner points out that the prior art need not explicitly recite a property to anticipate the instant invention. For instance, example 6 discloses a composition comprising 35% PPG (compatibilizing agent); 20% PEG-8000 (immobilizing agent); 5% glycerin (humectant); 10% benzyl alcohol (immobilizing agent); 10% stearyl alcohol (immobilizing agent); 3% glyceryl stearate (dispersing agent); 3% sunflower oil (natural oil); 3% soy sterol; 10%

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dimethicone (emollient); 1% DC 1428. The directs applicant's attention to page 25 of the instant specification wherein applicant states that the immobilizing agent may be C14-C22 fatty alcohols and high molecular weight polyethylene glycols such as PEG 8000. Therefore, the composition comprises 20% PEG-8000, 10% benzyl alcohol (C22 fatty alcohol); and 10% stearyl alcohol (C18 fatty alcohol) for a total of 40% of a immobilizing agent which falls within the claims range of 30-90%. Therefore, the composition falls within the claimed ranges of 1-40% of an emollient; 1-20% of a humectant; 30-90% of a immobilizing agent; and 1-40% of a compatibilizing agent. Thus, the prior art teaches the same components in the same weight percent and therefore the properties claimed, i.e. the composition is in a single haste at 45-80° C, must be the same since "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Note 2112 wherein the examiner is required to show and reasonable rationale for inherency and the burden shifts to applicant to show the difference. The examiner provided a reasonable rationale of inherency in the office action; however applicant has not provided any evidence showing the contrary. Thus, the rejection is maintained.

With regard to the recitation that the composition contains no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature, the examiner points out that about 50% of the components, PEG-8000, stearyl alcohol, and benzyl alcohol are solid at room temperature and less than about 50% of the components, PPG, glycerin, dimethicone, sunflower oil, etc. are liquid at room temperature. The

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property of being solid or conversely liquid at room temperature is an inherent property of the component itself.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzyski et al are maintained.

The disclosure of Krzyski et al has been delineated above. Krzyski et al teach using about 1 to about 20% of an emulsifying surfactant having an HLB range greater than 7 and 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal); and fatty esters.

Krzyski does not specifically teach the instantly claimed 1 to 1 ratio of silicone to dispersing agent.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the ratio of silicone to dispersing agent in view of the guidance provided by Krzyski et al. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments are similar to those made regarding the anticipation rejection.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. These arguments have been addressed above. It is the examiner's position that Krzysik is not deficient in the teaching of a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and a composition wherein 85% of the components form a single phase. Thus, the rejection is maintained.

The rejection of claims 23-24 and 55-56 under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzyski et al in view of Elias et al (5,643,899) are maintained.

The disclosure of Krzyski et al has been delineated above. Krzyski teaches the use of various actives in the skin barrier composition such as natural moisturizing agents and skin protectant that protect injured or exposed skin and mucous membrane. See page 16.

Krzyski et al do not teach glucosylceramide.

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Elias teaches irritations of the skin and mucous membrane caused by disrupted or dysfunctional epidermal barrier are treated or prevented by topical application of a formulation comprising epidermal lipid species such as cholesterol, an acylceramide, a ceramide, and essential and nonessential fatty acids. Elias teaches these combinations are effective both as moisturizing agents and agents for the restoration of barrier function and may be further enhanced by the use of known moisturizers such as petrolatum and glycerine. See abstract. The acylceramide in the composition may be replaced by a glycosylceramide such as glucosylceramide. See column 5, lines 45-50, examples, and 13-14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Krzyski et al and Elias et al and further add a glucosylceramide in the Krzyski's skin barrier composition. One would have been motivated to add glucosylceramide with the expectation of success since Elias teaches the use of natural lipid species treats and prevents damage to the skin and mucous membrane and Krzyski teaches the additional use of active agents such as natural moisturizing agents and skin protectants that protect the skin and mucous membrane.

Response to Arguments

Applicant's arguments are similar to those made regarding the anticipation rejection.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. These arguments have been addressed above. It is the examiner's position that Krzysik is not deficient in the teaching of a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and

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a composition wherein 85% of the components form a single phase. Thus, Elias is not relied upon to cure this deficiency. Thus, the rejection is maintained for the reasons of record.

The rejection of claims 14 and 33 under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzyski et al in view of Mitchnick et al (6,103,267) are maintained.

The disclosure of Krzyski et al has been delineated above. Krzyski teaches the use of an emulsifying surfactant having an HLB range greater than 7. Krzyski teaches the surfactant may be glyceryl stearate, glycol stearate, or an emulsifying wax. See page 5, second paragraph.

Formula 6 utilizes glyceryl stearate and DC 1428 (a silicone gum surfactant).

Krzyski et al do not teach the instant surfactant (dispersing agent).

Mitchnick teaches a dispersion comprising at least one water-soluble component and oily components such as silicone. See abstract. Mitchnick teaches the water-in-silicone dispersions comprise from about 0.5% to about 7.5% and more preferably from about 1% to about 5%, of an surface active agent for dispersing the discontinuous aqueous phase into the continuous silicone phase. Mitchnick teaches a wide variety of surface active agents may be employed and known and conventional emulsifiers/surfactants that provide the dispersion characteristics include non-silicone-containing emulsifiers/surfactants, silicone emulsifiers/surfactants, and mixtures thereof. Mitchnick teaches a wide variety of silicone surface-active agents within the low HLB range are useful. The silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains containing moieties derived from both ethylene

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oxide and propylene oxide. Nonlimiting examples of dimethicone copolyols and other silicone surfactants useful as emulsifiers herein include polydimethylsiloxane polyether copolymers with pendant polyethylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant polypropylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant mixed polyethylene oxide and polypropylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant mixed poly(ethylene)(propylene)oxide sidechains, etc. Examples of commercially available dimethicone copolyols include Dow Corning 190, 193, Q2-5220, 2501 Wax, 2-5324 fluid, and 3225C. Non-silicone emulsifiers include glyceryl stearate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Krzyski et al and Mitchnick et al and utilize a dimethicone silicone surfactant. One would have been motivated to utilize any known surfactant known to those skilled in the art since Mitchnick teaches the functional equivalency of the surfactants taught in Krzyski (glyceryl stearate) and dimethicone surfactants. Further, a skilled artisan would have expected similar results since Krzysik teaches the use of a silicone emulsifier (DC 1428). Thus, the substitution of the prior art's surfactants with the instant silicone surfactant would have been obvious to those skilled in the art in view of Mitchnick's teachings. A skilled artisan would have reasonably expected success in the instant combination since Krzyski's teaches surfactants with an HLB of less than 7 and Mitchnick teaches the silicone surfactants have low HLBs. Lastly, although Mitchnick does not teach the instant PEG-12 dimethicone, absent the unexpectedness of the instant dimethicone surfactant versus the prior art's dimethicone surfactants, it would have been obvious to utilize any dimethicone surfactant (which

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is a silicone compound having an oxyethylenated and/or oxypropylenated chain) that is commercially available.

Response to Arguments

Applicant's arguments are similar to those made regarding the anticipation rejection.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. These arguments have been addressed above. It is the examiner's position that Krzysik is not deficient in the teaching of a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and a composition wherein 85% of the components form a single phase. Thus, Mitchnick is not relied upon to cure this deficiency. Thus, the rejection is maintained for the reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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The provisional rejections of claims 1-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30, 32-60 of copending Application No. 10/659969 and claims 1-59 of 10/659862 are maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Independent claim 31 is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of a silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659862 is directed to a tissue paper comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1%

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to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659862 independent claim 31 is directed to a tissue paper comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659969 is directed to a absorbent substrate comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

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Copending 10/659969 independent claim 32 is directed to a tissue paper comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

The difference between the instant claims and those claimed in the copending application is '969 and '862 are directed to absorbent products whereas the instant claims are directed to a composition. However, the instant claims and copending applications are obvious over each other since the absorbent products claimed in '969 and '862 comprise the instant composition. Further, it should be noted that the dependent claims and the copending dependent claims are substantially similar in scope, i.e. the same emollient, the same immobilizing agent, the same compatibilizing agent, and the same humectants are claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The applicant argues that the double patenting rejections are premature and directs the examiner's attention to MPEP §804.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The examiner notes MPEP §804; however the rejection is maintained since the

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instant application is not in condition for allowance and the provisional rejections are not the only remaining rejections of record.

The rejection of claims 1-10, 12-13, 25-32, 34-41, 43, 52-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-33 US 5,869,075 are maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient (A), from about 1% to about 20% of a humectant (B), from about 30% to about 90% an immobilizing agent (C), and from about 1% to about 40% of a compatibilizing agent (D) wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Independent claim 31 is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of a silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

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US '075 independent claim 16 is directed to a softening composition comprising from about 30 to about 90 weight percent hydrophilic solvent (D), from about 10 to about 50 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater (C), and from about 5 to about 40 weight percent of a C.sub.14 to C.sub.30 fatty alcohol (A), said composition having a melting point from about 30.degree. C. to about 70.degree. C. and a penetration hardness of from about 5 millimeters to about 360 millimeters. Claim 17 is directed to the hydrophilic solvents selected from the group consisting of water, propylene glycol, low molecular weight polyethylene glycol, glycerin, sorbitol, hydrogenated starch hydrolysate and silicone glycol. Dependent claim 23 is directed to the composition comprising about 15 weight percent propylene glycol (D), about 50 weight percent high molecular weight polyethylene glycol (C), about 10 weight percent cetyl alcohol (A), and about 25 weight percent hydrogenated starch hydrolysate (B). Dependent claim 29 is directed to a composition comprising about 35 weight percent propylene glycol (D), about 20 weight percent high molecular weight polyethylene glycol (C), about 10 weight percent behenyl alcohol (C), about 10 weight percent stearyl alcohol, about 10 weight percent of a mixture of glyceryl and glyceryl polyacrylate (B), and about 10 weight percent dimethicone (A). Dependent claim 30 is directed to a composition comprising about 30 weight percent propylene glycol, about 15 weight percent high molecular weight polyethylene glycol, about 10 weight percent behenyl alcohol, about 10 weight percent stearyl alcohol, about 15 weight percent hydrogenated starch hydrolysate, about 5 weight percent of a mixture of glyceryl polyacrylate, propylene glycol, cyclomethicone, dimethiconol, and polysorbate 20 (dispersing agent), and about 10 weight percent dimethicone.

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The difference between the instant claims and those claimed in the US '075 is US '075 independent claim 16 does not claim a the instant combination of (A), (B), (C), and (D). However, the dependent claims claim the instant combination. With regard to instant claim 31, US '075 does not claim the instant silicone emollient. However, dependent claims claim dimethicone in the same weight percent and thus rendering similar subject matter as claimed in claim 31. Therefore, the instant claims and US '075 are directed to similar subject matter.

Response to Arguments

Applicant argues that US '075 does not claim a composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Lastly, applicant argues that the disclosure of the patent may not be used to make the rejection.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The examiner points out that claim 1 is directed to a composition comprising a) about 30 to about 90 weight percent hydrophilic solvent, b) from about 10 to about 50 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater, and c) from about 5 to about 40 weight percent of a C 14 to C 30 fatty alcohol wherein the composition having a melting point from about 30-70 degrees C and a penetration hardness of from about 5 millimeters to about 360 millimeters. Dependent claim 23 is directed to a composition comprising about 15% propylene glycol, about 50% high molecular weight polyethylene glycol, about 10% cetyl alcohol, and about 25% hydrogenated starch hydrolysate.

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Thus, the composition contains no less than 50% components that are solid at room temperature, i.e. 50% high molecular weight PEG and 10% cetyl alcohol, and less than 50% of the components are liquid at room temperature, i.e. 15% PPG, 25% hydrogenated starch hydrolysate. The property of being solid or conversely liquid at room temperature is an inherent property of the component itself. The fact that US '075 has not explicitly claimed this inherent property does not differentiate the subject matter claimed. Therefore, US '075 claims similar subject matter as claimed in the instant application and the rejection is maintained.

Lastly, applicant argues that the disclosure of the patent may not be used to make the rejection. The examiner acknowledges that the disclosure of a US patent may not be used to reject the claims under double patenting unless the examiner is relying on the disclosure to define a term. However, in instant case the examiner has not relied on the disclosure and the argument is moot.

The rejection of claims 1, 4-10, 13, 1517, 21-22, 25, 26-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of US 6475197 are maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature,

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and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Independent claim 31 is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of a silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

US '197 claims body facing material having an outer surface, wherein said outer surface of said body facing material has a composition that enhances skin barrier consisting of: from about 10 to about 90 weight percent hydrophilic solvent (D); from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater (C); from about 1 to about 30 weight percent of a C.sub.14 to C.sub.30 or greater fatty alcohol (A); from about 0.5 to about 10 weight percent of humectant (B); from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7; from about 0.1 to about 10 weight percent of sterol or sterol derivative; and, from about 0.1 to about 30 weight percent of natural fats or oils. Claim 2 is directed to a composition that has a melting point from about 30.degree. C. to about 100.degree. C. Claim 4 is directed to a composition that has a penetration hardness of from about 5 millimeters to about 360 millimeters. The dependent claims are directed to the instant humectant (glycerin), PEG with the

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instant molecular weight; PPG as the compatibilizing agent, the instant sterols, and instant fats and oils.

The difference between the instant claims and the claims of US '197 is US '197 directed to absorbent products whereas the instant claims are directed to a composition. However, the instant claims and copending applications are obvious over each other since the product comprise the instant composition.

Response to Arguments

Applicant argues that US '197 does not claim a composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The examiner points out that claim 1 is directed to a composition consisting from about 10-90% hydrophilic solvent (compatibilizing agent); from about 5-95% high molecular weight polyethylene glycol having a molecular weight of about 720 or greater (immobilizing agent); from about 1-30% of a C14 to C30 or greater fatty alcohol (emollient); from about 0.5-10% of humectant; from about 1-20% of oil-in-water emulsifying surfactant having an HLB range greater than 7; from about 0.1-10% of sterol or sterol derivative; and, from about 0.1 to about 30% of natural fats or oils. The examiner points out that it is within the skill of an artisan to manipulate the amount to yield the instant claimed composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature. For instance, US '197 claims 5% as the lower limit of the hydrophilic solvent which is liquid at room temperature; 95% as the maximum limit of the

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high molecular weight PEG which is solid at room temperature (note applicant claims “about 90%” and applicant has not defined “about” to mean exactly in the specification, note MPEP 2111.01 IV); 10% as the maximum weight of the humectant, which is liquid at room temperature; and 1% as the lower limit of the fatty alcohols, which are solid at room temperatures. Clearly the maximum and minimum ranges claimed in US ‘197 yield a composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature. Therefore, US ‘197 claims similar subject matter as claimed in the instant application and the rejection is maintained.

Miscellaneous Remarks

The examiner notes the assignee and inventors have numerous pending applications and US patents. Thus, the examiner requests the applicant identify any applications or patents that may have similar subject matter.

Conclusion

All the claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Sharmila S. Gollamudi
Primary Examiner
Art Unit 1616

SSG